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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,747	12/03/2001	Shimon Slavin	02/23156	1863

7590 11/17/2004

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,747	SLAVIN, SHIMON	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-40,42, 43 and 45-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-40,42,43 and 45-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The **examiner** of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Michail Belyavskyi, Group Art Unit 1644, Technology Center 1600

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/06/04 has been entered.

Claims 20-40, 42-43 and 45-69 are pending.

Upon further consideration, the prior art search has been extended to include claims 22-26 and 35-38.

Claims 20 - 40, 42, 43 and 45- 69 are under consideration in the instant application.

3. If applicant desires priority under 35 U.S.C. 119 (e) or 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

4. The disclosure is objected to because of the following informalities: A handwritten changes has been found at page 50, line 6 of the instant specification.

Appropriate correction is required.

The following new ground of rejections are necessitated by the Amendment, filed on 08/06/04

5. The following is a quotation of the second paragraph of 35 U.S.C. 112.
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6 . Claims 20 - 40, 42, 43 and 45- 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 20 is indefinite and ambiguous in the recitation of "... in a regimen selected so as to cause partial engraftment of ...". The characteristics and metes and bounds of " a regimen selected so as to cause partial engraftment are unclear and indefinite. Moreover, the Specification on overlapping pages 9-10 disclosed several regimens, but on page 19, line 19-20 disclosed that not all regimens are effective. It is unclear what regimen will cause partial engraftment of administered lymphocytes.

8. Dependent claim 21 recites "minimal GVHD". There is insufficient antecedent basis for this limitation in the claims, since base Claim 20 does not recite "minimal GVHD".

8. Claim 69 is indefinite and ambiguous in the recitation of " said regime selected so as to cause permanent engraftment of stem cell". It is noted that independent claim 20 recites " a regime to cause partial engraftment of lymphocytes ". It is unclear if the same regimen that cause "partial engraftment of lymphocytes" will be also used to cause "a permanent engraftment of stem cell" or there are at least two different regimen.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 20 - 40, 42, 43 and 45- 69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection**.

11. (i) " A method of treating a human cancer patient having a hematopoietic malignancy, comprising a method steps as recited in claim 20 ; " partial engraftment of said lympocytes", claimed in claim 20, step a); (ii) " the method of treating a human cancer patient having a hematopoietic malignancy, wherein GVHD is mucocutaneous GVHD , or wherein said GVHD involves the oral cavity or the skin or does not substantially involve the intestines or liver or wherein GVHD is acute or chronic GVHD, claimed in claims 45-51 respectively; (iii) "the method of treating a human cancer patient having a hematopoietic malignancy, wherein said dose of lymphocytes is effected during a period selected from the range of 90-124 days following said stem cell transplantation, or "said dose of stem cell effected following administering to the patient of lymphocytes" claimed in claims 60-62 respectively; (iv) "the method of treating a human cancer patient having a hematopoietic malignancy wherein said administering to the patient of lymphocytes is only effected during a period, selected from the group recited in claim 64, claimed in claim 64; (v) a method of treating a human cancer patient having a hematopoietic malignancy, wherein regimen selected so as to cause GVHD in the patient and further selected so as to cause permanent engraftment of stem cell, claim in claim 69 represents a departure from the specification and the claims as originally filed and applicant has not pointed out where the support comes from.

The specification and the claims as originally field only support for a method of treating a human cancer patient, comprising method steps as recited in originally filed claim 1-3.

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20 - 40, 42, 43 and 45- 69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,928,639. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-18 of US Patent '639 recites a method of treating a human cancer patient , having undergone a malignant cell debulking, comprising a steps of administering a HLA-compatible, allogeneic lymphocytes and further administering stem cells.

US Patent'639 does not explicitly teaches administration of allogenic lymphocytes in a regime which cause GVHD from a range of grade I to grade II, i.e. very mild or minimal GVHD.

However, it is noted that claim 2, step c) explicitly recited that " if no or insufficient GVHD response develops in said patient, escalating said treatment by performing the next step...".

It is clear that both the prior art and applicant administer the same treatment to achieve the same results in the same patient. Therefore it would be obvious to one of ordinary skill in the art at the time the invention was made to conclude that a regime of administering of allogenic lymphocytes disclosed in US Patent '639 should be selected so as to cause minimal or mild GVHD.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
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November 12, 2004

Christina Chan

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